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APPLICATION NUMBER	FILING DATE	FIRST NAMED APPLICANT	ATTY. DOCKET NO.
08/485,129	06/07/95	WALLACH	D WALLACH-5B
EXAMINER			
18M1/1209			
BROWDY AND NEIMARK 419 SEVENTH STREET N W WASHINGTON DC 20004		SCHWADRON, R ART UNIT	PAPER NUMBER 9
1816		DATE MAILED: 12/09/96	

This is a communication from the examiner in charge of your application.  
COMMISSIONER OF PATENTS AND TRADEMARKS

### OFFICE ACTION SUMMARY

Responsive to communication(s) filed on 10/7/96

This action is FINAL.

Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 D.C. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

#### Disposition of Claims

Claim(s) 11-14, 33-45 is/are pending in the application.

Of the above, claim(s) 14, 39, 42, 45 is/are withdrawn from consideration.

Claim(s) \_\_\_\_\_ is/are allowed.

Claim(s) 11-13, 33-38, 40, 41, 43, 44 is/are rejected.

Claim(s) \_\_\_\_\_ is/are objected to.

Claim(s) \_\_\_\_\_ are subject to restriction or election requirement.

#### Application Papers

See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

The drawing(s) filed on \_\_\_\_\_ is/are objected to by the Examiner.

The proposed drawing correction, filed on \_\_\_\_\_ is  approved  disapproved.

The specification is objected to by the Examiner.

The oath or declaration is objected to by the Examiner.

#### Priority under 35 U.S.C. § 119

Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

All  Some\*  None of the CERTIFIED copies of the priority documents have been

received.

received in Application No. (Series Code/Serial Number) \_\_\_\_\_

received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

\*Certified copies not received: \_\_\_\_\_

Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e).

#### Attachment(s)

Notice of Reference Cited, PTO-892

Information Disclosure Statement(s), PTO-1449, Paper No(s). \_\_\_\_\_

Interview Summary, PTO-413

Notice of Draftsperson's Patent Drawing Review, PTO-948

Notice of Informal Patent Application, PTO-152

-SEE OFFICE ACTION ON THE FOLLOWING PAGES-

15. Applicant's election with traverse of Group I, claims 11-13,33-38,40,41,43,44 in Paper No. 9 is acknowledged. The traversal is on the ground(s) that are elucidated in Paper No. 9. This is not found persuasive because of the following reasons. Regarding applicants comments on page 2 of Paper No. 9, the relevant DNA can be easily isolated from the host cell based on the knowledge of the DNA sequence that was used to insert the pertinent DNA into the vector/host cell when said vector/host cell was originally created (eg. see specification, page 11, last paragraph). Furthermore, the claimed host cells could be modified (eg. by removing or inserting DNA) for the production of fusion proteins or chimeric molecules containing various domains of TBP-II. Regarding applicants comments on page 2 of the instant amendment, the M.P.E.P. § 803 (Rev. 1, Sept. 1995, page 800-4) states that: "For purposes of the initial requirement, a serious burden on the examiner may be *prima facie* shown if the examiner shows by appropriate explanation either separate classification, separate status in the art, or a different field of search". The restriction requirement enunciated in the previous Office Action meets this criterion and therefore establishes that serious burden is placed on the Examiner by the searching of additional Group II. Regarding applicants comments on page 3 of the instant amendment, no allowable claims are present in the instant application. Regarding applicants comments on page 4 of the instant amendment, there are no claims present in application 07/934,443 which read on the instant invention (eg. DNA). There are also no allowed claims in said application (eg. said claims are currently in an interference proceeding).

The requirement is still deemed proper and is therefore made FINAL.

16. Claims 14,39,42,45 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention, the requirement having been traversed in Paper No. 8.

17. Claims 11-13,33-38,40,41,43,44 are under consideration.

18. Drawings have been submitted which fail to comply with 37 CFR 1.84. Please see the enclosed form PTO-948.

The drawings are considered to be informal because they fail to comply with 37 CFR 1.84(a)(1) which requires black and white drawings using India ink or its equivalent.

Photographs and color drawings are acceptable only for examination purposes unless a petition filed under 37 CFR 1.84(a)(2) or (b)(1) is granted permitting their use as formal drawings. In the event applicant wishes to use the drawings currently on file as formal drawings, a petition must be filed for acceptance of the photographs or color drawings as formal drawings. Any such petition must be accompanied by the appropriate fee as set forth in 37 CFR 1.17(h), three sets of drawings or photographs, as appropriate, and, if filed under the provisions of 37 CFR 1.84(a)(2), an amendment to the first paragraph of the brief description of the drawings section of the specification which states:

The file of this patent contains at least one drawing executed in color. Copies of this patent with color drawing(s) will be provided by the Patent and Trademark Office upon request and payment of the necessary fee.

Color photographs will be accepted if the conditions for accepting color drawings have been satisfied.

19. The use of the trademarks AFFIGEL-10, AQUAPORE, SYNCHROPAK, MONO-Q, TWEEN 20 has been noted in this application. It should be capitalized wherever it appears and be accompanied by the generic terminology.

Although the use of trademarks is permissible in patent applications, the proprietary nature of the marks should be respected and every effort made to prevent their use in any manner which might adversely affect their validity as trademarks.

20. The abstract of the disclosure is objected to because it does not disclose the claimed invention (eg. DNA encoding TBP-II). Correction is required. See MPEP § 608.01(b).

21. 35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

22. Claims 11,33-36 are rejected under 35 U.S.C. § 101 because the claims encompass products of nature, and are thus not directed to patentable subject matter. The claimed DNA

encompasses DNA identical to naturally occurring DNA encoding TBP-II. Applicant can overcome this rejection by amending the claims to read on an isolated or purified DNA (assuming support for such language is found in the specification).

23. Claims 11-13,33-38,40,41,43,44 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

There is no support in the specification as filed for the DNA of claim 11. There is no support in the specification as originally filed for the recitation of "amino acid sequence substantially corresponding" in said claim. There is no support in the specification as original filed for the DNAs of claims 35 and 36.

24. Claims 11-13,33-38,40,41,43,44 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The specification as filed does not adequately teach how to make the claimed nucleic acids. It is well established that one cannot make that of which one has no conception. The specification discloses a partial protein sequence, and offers it up as enablement of nucleic acids encoding the isolated proteins and a broad range of other possible species. There is no disclosure of the complete sequence of any protein, nor is there any disclosure of even a single nucleic acid that would meet the limitations of the claims. Thus, there is no teaching of structure that the artisan could use as a guide in making the claimed nucleic acids. In the absence of any working examples, any guidance as to the structure of the claimed nucleic acids, and the unpredictability inherent in making nucleic acids to encode proteins which are defined almost solely by function, it would require undue experimentation to practice the claimed invention. It was found in Amgen v. Chugai, 18 USPQ 2d 1017 at 1021, that:

"A gene is a chemical compound, albeit a complex one, and it is well established in our law that conception of a chemical compound requires that the inventor be able to define it so as to distinguish it from other materials, and to describe how to obtain it. See Oka, 849 F. 2d at 583,

7 USPQ2d at 1171. Conception does not occur unless one has a mental picture of the structure of the chemical, or is able to define it by its method or preparation, its physical or chemical properties, or whatever characteristics sufficiently distinguish it. It is not sufficient to define it solely by its principal biological property, *e.g.*, encoding human erythropoietin, because an alleged conception having no more specificity than that is simply a wish to know the identity of any material with that biological property. We hold that when an inventor is unable to envision the detailed constitution of a gene so as to distinguish it from other materials, as well as a method for obtaining it, conception has not been achieved until reduction to practice has occurred, *i.e.*, until after the gene has been isolated.".

This position was further supported in Fiers v. Sugano, where it was stated: "An adequate written description of a DNA requires more than a mere statement that it is part of the invention and reference to a potential method for isolating it; what is required is a description of the DNA itself" (26 USPQ2d 1601 at 1606). Thus, the instant specification does not adequately describe, and therefore *cannot* adequately teach how to make, the claimed invention. The Examiner also cites the decision In re Deuel, 34 USPQ2d 1210, in which it was found that disclosure of a partial protein sequence does not render obvious the DNA encoding that sequence; the situation here is analogous, in that applicants allege enablement of the claimed nucleic acids on the basis of the disclosure of a partial protein sequence, without having taught any particular structure for the claimed nucleic acids themselves.

Regarding claims 11,35 and 36, said claims recite functional properties of a particular protein encoded by a DNA wherein said DNA encompasses DNA other than the naturally occurring molecule. However, there is no disclosure in the specification of the particular region of the DNA that encodes that functional property. Thus it would require undue experimentation to produce the claimed DNAs because there is no guidance in the specification as to what portion of the DNA molecules encodes the particular domain mediating the functional activity. The claims encompass nucleic acids encoding innumerable mutants, variants, and derivatives. In the express absence of any information as to the complete structure of the encoded proteins, as well as any information as to the structure-function relationship of the proteins, it would require undue experimentation to practice the invention in a manner commensurate in scope with the claims, that is, to predict which of the innumerable encompassed nucleic acids would reasonably be expected to encode functional proteins.

The specification discloses an isolated protein(s) which share part of a common amino acid sequence near the amino terminus of the protein. Only a partial amino acid sequence is disclosed. The full amino acid sequence of the proteins is unknown. There is no disclosure in the specification as to whether the particular amino acid sequences listed on pages 23 are derived from the same molecule or that the molecule is found as four different but related molecules. There is no guidance in the specification as to whether the four potential forms of TBP-II are functionally active or the nature of the identity of the functionally active molecule. The specification proposes that using oligonucleotides, one can obtain DNA encoding the disclosed proteins. However, there is no disclosure in the specification of the identity of said oligonucleotides. There is also no evidence of record that the amino acid sequence disclosed in the specification can be used to produce oligonucleotides that could have been used to isolate TBP-II DNA.

The Examiner notes that the description of claimed nucleic acids via a single biological function is similar to the situation in Ex parte Maizel (27 USPQ2d 1662 at 1665) in which it was found that:

Appellants have not chosen to claim the DNA by what it is but, rather, by what it does, i.e., encoding either a protein exhibiting certain characteristics, *or* a biologically functional equivalent thereof. Appellants' claims might be analogized to a single means claim of the type disparaged by the Court of Customs and Patent Appeals in *In re Hyatt*, 708F.2d 712, 218 USPQ 195 (Fed. Cir. 1983). The problem with the phrase "biologically functional equivalent thereof" is that it covers any conceivable means, i.e., cell or DNA, which achieves the stated biological result while the specification discloses, at most, only a specific DNA segment known to the inventor. Clearly the disclosure is not commensurate in scope with the claims."

In the instant case not only is the disclosure not commensurate in scope with the claims, the disclosure fails to present even a single operable species of the claimed invention.

25. Claims 11-13,33-38,40,41,43,44 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 11 is indefinite in the recitation of "substantially corresponding" because it is

unclear what this means or encompasses in the context recited in the claim. Claims 33 and 34 are indefinite in the recitation of "in accordance" because it is unclear what this means or encompasses in the context recited in the claims.

26. No claim is allowed.

27. Papers related to this application may be submitted to Group 180 by facsimile transmission. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). Papers should be faxed to Group 180 at (703) 305-7939.

28. Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Dr. Ron Schwadron whose telephone number is (703) 308-4680. The examiner can normally be reached Tuesday through Friday from 8:30 to 6:00.

The examiner can also be reached on alternative Mondays. A message may be left on the examiners voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the Examiner's supervisor, Ms Christina Chan can be reached on (703) 308-3973. Any inquiry of a general nature or relating to the status of this application should be directed to the Group 180 receptionist whose telephone number is (703) 308-0196.



RONALD B. SCHWADRON  
PRIMARY EXAMINER  
GROUP 1800

Ron Schwadron, Ph.D.

Primary Examiner

Art Unit 1816

December 9, 1996